

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

MARGARET HALTON PRIEST, Individually)		
and as Representative of the Estate of Noel)		
Lajoie Priest)		
Plaintiff,)		
vs.)		CIVIL ACTION NO. 1:15-CV-00822-LY
SANDOZ, INC.)		
Defendant.)		

**DEFENDANT SANDOZ INC.’S MOTION TO EXCLUDE
TESTIMONY OF RICHARD FRIEDLANDER, M.D. IN PART
WITH INCORPORATED MEMORANDUM OF LAW**

Defendant Sandoz Inc. (“Sandoz”) submits this Motion to Exclude testimony of Plaintiff’s expert Richard Friedlander, M.D. in part, pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and this incorporated Memorandum of Law in support thereof, and states as follows:

I. INTRODUCTION

Plaintiff has identified Richard P. Friedlander, M.D. (“Dr. Friedlander”), a New York cardiologist, as an expert witness to support the claim that Mr. Priest developed amiodarone-induced pulmonary toxicity (“AIPT”) following his short term, low dose use of amiodarone. Dr. Friedlander is further offered to opine that AIPT was the primary factor causing Mr. Priest’s death. Finally, Dr. Friedlander’s report and testimony contend that Mr. Priest’s life-expectancy was shortened by his alleged AIPT. *See* Expert Report of Richard P. Friedlander, M.D. (“Friedlander Report”), attached as **Exhibit A**, at p. 2-4.¹

¹ Because it contains private medical information regarding Plaintiff’s decedent, Dr. Friedlander’s Report was filed under seal as Exhibit A to Defendant’s Motion to Seal filed contemporaneously herewith, excerpts of Dr. Friedlander’s deposition were filed as Exhibit B to the Motion to Seal, and a CT report of Mr. Priest was filed as Exhibit D to the Motion to Seal. Throughout this memorandum of law, any references to Exhibit A, Exhibit B, or

Dr. Friedlander's report and his opinions, however, are neither medically sound nor legally admissible. Dr. Friedlander's report is riddled with inaccuracies and misleading statements, many of which Dr. Friedlander recanted and attempted to recast in his deposition testimony, blaming the Plaintiff's lawyers for "unartfully wording" his report when they wrote it. But when his opinions were more fully explored in deposition, it became clear both his diagnosis and cause of death opinions are speculative and unreliable. Dr. Friedlander is simply not qualified to make a diagnosis of AIPT in the first place, and his opinion that amiodarone caused the sequence of events leading to Mr. Priest's death is contrived and unsupported by the contemporaneous medical record or any medical literature that he could identify.

Dr. Friedlander lacks the requisite education, training and experience as required by Fed. R. Evid. 702 to offer an opinion as to Mr. Priest's alleged pulmonary diagnosis, much less the necessary experience and supporting facts to opine that AIPT was the cause of his death. In deposition, he admitted he had not reviewed Mr. Priest's prior medical records, nor any of the radiology films he ostensibly relies upon. The scant literature he relied upon was provided by Plaintiff's counsel, and he conducted no independent research to determine if his opinion was supported by relevant peer-reviewed literature. The issues described above are not mere fodder for cross-examination, but rather go directly to the admissibility of a medical expert's opinion. Dr. Friedlander's opinions would be unhelpful to a jury because they lack a reliable basis and are entirely speculative.

Accordingly, Dr. Friedlander's opinions should be excluded or significantly limited as noted in the proposed order submitted herewith, because his opinions on Mr. Priest's diagnosis and his opinions related to cause of death fail to meet the requirements for admission of expert evidence mandated by Fed. R. Evid. 702 and *Daubert*. The case law of this jurisdiction and the

Exhibit D refer to the documents are attached to the Motion to Seal as Exhibits A, B, and D.

5th Circuit consistently excludes or limits experts who overreach in their testimony and opinions, and the Court should do the same here.

II. LEGAL STANDARD FOR ADMISSION OF EXPERT TESTIMONY

To be admissible, proposed expert testimony must satisfy the expert admissibility standards under Federal Rule of Evidence Rule 702, which provides in pertinent part:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

In *Daubert*, the United States Supreme Court provided the analytical framework for this determination under Rule 702. *See Daubert*, 509 U.S. 579, 589-95 (1993); *see also U.S. v. Hicks*, 389 F.3d 514, 525 (5th Cir. 2004). Under this framework, district courts “act as gatekeepers overseeing the admission of scientific and non-scientific expert testimony.” *Burleson v. Texas Dep’t of Criminal Justice*, 393 F.3d 577, 583 (5th Cir. 2004) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999)); *see also In re Silica Products Liability Litigation*, 398 F. Supp. 2d 563, 621 (S.D. Tex. 2005). In addition, “the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 275 (5th Cir. 1998); *see also In re Silica*, 398 F. Supp. 2d at 620.

Rule 702 requires the trial court to first determine if the purported expert witness is qualified to give the proffered testimony. *U.S. v. Abdallah*, 629 F. Supp. 2d 699, 749 (S.D. Tex. 2009). To be qualified as an expert, a witness must “possess specialized knowledge, skill, experience, training, or education.” *Id.* (citing Fed. R. Evid. 702). Thus, “[t]he court must determine whether the proposed expert’s training or experience are sufficiently related to the

issues and evidence before the court that the expert's testimony will assist the trier of fact." *Id.*

If the purported expert is qualified, then the Court must determine the expert's testimony is both relevant and reliable before it will be admitted. *Abdallah*, 629 F.Supp. 2d. at 749-50 ("The court "must ensure that the expert uses reliable methods to reach his opinions; and those opinions must be relevant to the facts of the case." (citing *Guy v. Crown Equip. Corp.*, 394 F.3d 320, 325 (5th Cir.2004))). The proponent of the expert testimony bears the burden of demonstrating the expert's findings and conclusions are reliable and admissible under Rule 702. *See Moore*, 151 F.3d at 276. This burden is not satisfied merely by the expert's "assurances that he has utilized generally accepted scientific methodology." *Id.* Rather, the proponent bears the burden to "prove by a preponderance of the evidence that the testimony is reliable." *Id.* Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Daubert*, 509 U.S. at 591-92, 113 S.Ct. 2786 (internal citations and quotation marks omitted). Here, the Plaintiff cannot meet that burden with regard to Dr. Friedlander's opinions.

As the gatekeeper of medical or scientific expert testimony, the trial court's overarching consideration "is the scientific validity – and thus the evidentiary relevance and reliability – of the principles that underlie a proposed submission." *Daubert*, 509 U.S. at 594-95. "The second prong of the gate-keeping role requires an analysis of whether the expert's reasoning or methodology can be properly applied to the facts at issue, that is, whether the opinion is admissible." *Daubert*, 509 U.S. at 591-92. Courts must independently determine whether the facts and data on which an expert's opinion is based on "otherwise reasonably reliable." *Dow v. McFarlane*, 207 S.W.3d 53, 62 (2006). Further, a purported expert witness's "use of a general methodology cannot vindicate a conclusion for which there is no underlying . . . support." *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999) (Physical Medicine and

Rehabilitation physician who offered testimony that customer's fall caused hormonal damage leading to fibromyalgia was not sufficiently reliable, because it was unsupported by a specific reliable methodology and was contradicted by the general level of current medical knowledge).

Applying these standards, an expert's opinion must be founded on substantial information, not mere conjecture or speculation, and there must be a rational basis for the opinion. *Id* at 310 (citing *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 711–12 (Tex. 1997) (“possibility, speculation, and surmise” are insufficient to support expert testimony regarding medical causation)). Medical opinions based upon assumptions and speculation, unsupported by evidence in the patient's medical record, are not reliable and should not be admitted. Here, the diagnosis and causation opinions set forth in Dr. Friedlander's report and testified to in Dr. Friedlander's deposition do not meet these standards and must be excluded or severely limited so as not to mislead the jury and incurably prejudice the Defendant.

III. ARGUMENT

A. Dr. Friedlander's Report Should Be Excluded Because It Is Factually Inaccurate, Unreliable, and Misleading to the Jury.

Dr. Friedlander's Report should be excluded because the inaccuracies and misleading statements contained throughout it pose a significant risk of confusing the jury and render it unreliable. Admitting the report would require the jury to try and reconcile the incorrect statements in the report with Dr. Friedlander's revised opinions in his deposition and at trial, or to ignore the report outright and simply rely on his testimony. Thus, the report would not be helpful to the jury in deciding the issues in this case. For example:

- The report states he had reviewed the deposition of Dr. Batrice, the attending physician in the final two hospitalizations and the physician who signed the death certificate. Friedlander Report, ¶ 1. However Dr. Friedlander admitted in deposition that he had not reviewed Dr. Batrice's deposition. August 3, 2017 Deposition of Dr. Richard Friedlander (“Friedlander Dep.”), attached as **Exhibit B**, at 240:2-13 (“No, that is a mistake in the report.”)

- Dr. Friedlander’s report misstates that Mr. Priest was diagnosed and treated for atrial fibrillation (“afib”) and that is why the amiodarone was prescribed. Report p. 2, ¶ 2. Dr. Friedlander readily admitted in deposition that this is not correct. Friedlander Dep. p. 123:16- 124:2 (“But, yes...he was treated for ventricular arrhythmias, not atrial arrhythmias.”)
- The report also falsely states the use of amiodarone to treat Mr. Priest was an “off label” use of the drug. Report p. 2, ¶ 2. However in deposition Dr. Friedlander admits the use was not “off label”. *Id.* at 124:17-18 (“It is not an off label use...”).
- Dr. Friedlander’s report (p. 2, ¶ 3) presents inaccurate facts concerning Mr. Priest’s symptoms on July 23, 2013 when Dr. Friedlander asserts he was first suffering from amiodarone toxicity. The report states Mr. Priest presented with weight loss at that visit, but the records show he had actually gained 5 lbs since starting amiodarone. Friedlander Dep. p. 148:22-25 (“Q: So between July 1 and July 23, doctor, he’s actually gained 5 pounds? A: That’s right.”)
- Dr. Friedlander’s report states Mr. Priest’s “dysphagia, medullary failure (etc.) “were natural and expected sequelae... from amiodarone toxicity.” Friedlander report p. 2, ¶ 5. But in deposition, Dr. Friedlander backed away from this statement, calling it “unartfully worded” and blaming the attorneys who drafted it. *Id.* at 271:7. He admitted Mr. Priest did not die from the natural sequelae of AIPT (Q: And that was not the path of Mr. Priest’s demise, was it? A: No, because he had an acute insult before that could happen.”) *Id.* at 272:8-23

Dr. Friedlander quickly offered that the plaintiff’s attorneys had drafted the report, although he is certain that he must have reviewed it if he signed it. *Id.* at 41:18-21. However, the same inaccuracies in the report also undercut the opinions Dr. Friedlander testified to at deposition.

The disclosure of expert witnesses and the requirements for an expert report are governed by Fed. R. Civ. P. 26(a)(2)(B), which states the “disclosure shall, with respect to a witness who is retained... be accompanied by a written report *prepared* and signed *by the witness.*” Fed. R. Civ. P. 26(a)(2)(B) (emphasis added). Based on the admitted errors and inaccuracies in the report, and Dr. Friedlander’s admission that he did not write it, it is clear the report does not meet the requirements of Fed. R. Civ. P. 26(a)(2)(B). The numerous inaccuracies and misstatements render the report inherently unreliable and not helpful to the jury. Accordingly, his report should be deemed inadmissible and excluded from the case.

B. Dr. Friedlander's Opinion Diagnosing Mr. Priest with AIPT Should Be Excluded Because He Is Not Qualified to Give It and It Is Not Based on Reliable Methodology.

When the requisite scrutiny described above is applied, Dr. Friedlander's lack of qualifications to opine about pulmonary diseases such as AIPT is apparent, and his opinion purporting to diagnose Mr. Priest with AIPT should be excluded. Dr. Friedlander lacks the relevant education, training or experience with treating pulmonary diseases to make the diagnosis asserted in this case. It is simply outside of Dr. Friedlander's specialty and experience. As additional grounds to exclude his diagnosis opinion, the methodology Dr. Friedlander used to arrive at this diagnosis opinion is inherently unreliable, and he admittedly failed to rule out other possible pulmonary disease processes which may appear similar on radiographs and CT and would also explain Mr. Priest's symptoms.

1. Dr. Friedlander's Qualifications Do Not Match the Opinions He Seeks to Offer.

Although Dr. Friedlander is a cardiologist, this alone does not qualify him to offer a clinical opinion about whether amiodarone caused or contributed to Mr. Priest's lung disease and death. A licensed medical doctor is not automatically qualified to testify as an expert on every medical question in every specialty. *See Christophersen v. Allied-Signal Corporation*, 939 F.2d 1106, 1112-1113 (5th Cir. 1991), cert. denied, 503 U.S. 912 (1992) (even though "expert has M.D. degree ... [t]hat alone is not enough to qualify him to give an opinion on every conceivable medical question"); *see also Broders v. Heise*, 924 S.W.2d 148, 152-53 (Tex. 1996) ("... a licensed medical doctor is not automatically qualified to testify as an expert on every medical question. The Court must closely scrutinize whether a witness's area of special knowledge or expertise matches the subject matter of the proffered expert testimony, and if not, it should be excluded.") *Carroll v. Otis Elevator Co.*, 896 F.2d 210, 212 (7th Cir. 1990) ("Whether a witness is qualified as an expert can only be determined by comparing the

area in which the witness has superior knowledge, skill, experience, or education with the subject matter of the witness's testimony.”)

While Dr. Friedlander may be a well-qualified cardiologist, he is admittedly not a pulmonologist with the specialized training in pulmonary disease to opine about the ultimate issue in this case, which is whether Mr. Priest had AIPT or some other pulmonary disease. (Friedlander Dep. P. 94:8-11) (“And you don’t hold yourself out as an expert in pulmonology, do you? A: No more than any other board certified internist...”) Dr. Friedlander is an attending cardiologist at Flushing Hospital Medical Center. *See* Curriculum Vitae of Richard P. Friedlander, M.D., attached as **Exhibit C**; *see also* Friedlander Dep at p. 93. He is the Medical Director of Cardiovascular Ultrasound at Empire Cardiac Monitoring and Medical Director of Echocardiographic Services at Doshi Diagnostic Services. *Id.* He was never trained on amiodarone. *Id.* at 114:18-20. None of his publications are even remotely related to the issues in this case. *Id.* at 100:10-20. He has done no specific research on Amiodarone prior to this litigation he just tries “to be current on the literature. But that doesn’t me[an] that [he] will read every article, and some of those articles are obviously about Amiodarone.” *Id.* at 96: 20-23.

Plaintiff has not established that Dr. Friedlander has the requisite experience and background to provide expert testimony on pulmonary toxicity or to diagnose Mr. Priest with AIPT, as is Plaintiff’s burden as the proponent of the expert testimony. While Dr. Friedlander has testified as an expert in deposition at least 75 times and at trial at least 125 times (*id.* at 12), he admits his history of expert testimony is “almost exclusively cardiology” and this case is his first instance testifying in a product liability case related to amiodarone. *Id.* at 32 and 22. That a proposed witness may be an expert in one area, does not *ipso facto* qualify him to testify as an expert in all related areas. *See Diviero v. Uniroyal Goodrich Tire Co.*, 919 F. Supp. 1353, 1356-57 (D. Ariz. 1996) (“If, however, scientific knowledge is necessary the expertise must be

coextensive with the particular scientific discipline.”) *Thomas*, 42 F.3d at 1269–70 and n.3; *Claar v. Burlington Northern Railroad Co.*, 29 F.3d 499, 502 (9th Cir.1994) (emphasis added) (“Expertise in the technology of fruit is not sufficient when analyzing the science of apples.”)

Based on Dr. Friedlander’s lack of relevant training and experience in pulmonary disease and amiodarone in particular, he is not qualified to opine in this case as to a diagnosis of amiodarone toxicity. In *Dukatt v. United States*, the proffered medical expert was a physician specializing in pain intervention and offered an opinion as to the standard of care in the orthopaedic treatment of a fractured ankle. *Dukatt v. United States*, No. EP-99-CA-339-DB, 2000 WL 33348770 (W.D. Tex., Dec. 8, 2000). The Court disallowed the expert even though he was board certified in orthopaedics, because he admittedly had no experience with the type of injury at issue and therefore lacked the specialized knowledge to render an opinion. Similarly in *Copley v. Smith & Nephew*, the district court excluded testimony of a purported medical causation expert whose specialty was in physical medicine and rehab but who had no education or experience in orthopaedics or neurology, which was the subject at issue in that bone screw case. No. Civ. A.H-97-2910, 2000 WL 223404, at *4 (S.D. Tex., Feb 2, 2000).

Like the proffered experts in *Dukatt* and *Copley*, Dr. Friedlander lacks the requisite qualifications in the specific field of pulmonology to be able to testify that Mr. Priest’s ingestion of amiodarone caused him to develop AIPT. His opinions on medical causation should therefore be excluded.

2. Dr. Friedlander’s Diagnosis Opinion Is Not Based on Reliable Methodology or Sufficient Medical Evidence.

In this case, the particular issue on which Plaintiff offers Dr. Friedlander’s testimony is whether, to a reasonable medical probability, Mr. Priest’s ingestion of amiodarone caused him to develop AIPT. The nature and function of prescription drugs and the causes of interstitial

lung disease clearly fall outside the common understanding of a layperson, and, as such, expert testimony is required to establish medical causation in this case. *Samuel v. Johnson & Johnson*, 2015 WL 10793724, at *4 (E.D. Tex. Aug 14, 2015) (the nature and function of prescription drugs is outside the common understanding of a layperson and thus, expert testimony is required to establish whether a drug caused plaintiff's injuries.)

It is well-established that testimony of an expert who fails to review sufficient material to support his opinions should be excluded as unreliable. For example, in *King v. Synthes*, an expert proposed to testify that a medical device manufacturer failed to meet FDA testing requirements in obtaining FDA clearance for the device. *See King v. Synthes (U.S.A.)*, 532 F. Supp. 2d 828, 830 (S.D. Miss. 2006). The court held the proffered testimony did not meet the rigors of *Daubert* because the primary basis underlying the opinions was the expert's review of documents plaintiff's counsel selected and his own interpretation of certain FDA requirements. *Id.* at 830, 834. Accordingly, the court excluded the expert's opinions because they were not "based upon appropriate methodology as *Daubert* commands." *Id.* at 836. The same result is justified here because Dr. Friedlander admittedly did not review all of and may not have even been provided all of the relevant medical records necessary to make a diagnosis. For example:

- **Dr. Friedlander has no idea if he was provided or reviewed all the medical records or the decedent's entire medical history.** Friedlander Dep. 42:15-21.
- **Dr. Friedlander was not familiar with Mr. Priest's pulmonary history before he offered his diagnosis opinion that he had pulmonary toxicity.** *Id.* at 151:14-17 (Q: Are you aware whether Mr. Priest had complaints of dyspnea prior to June 1, 2013? A: Specifically, I do not, it wouldn't surprise me if he had some complaints.)
- **Dr. Friedlander did not bother to determine how much amiodarone Mr. Priest had taken before Dr. Friedlander arrived at his diagnosis opinion.** *Id.* at 128:18-22. (Q: When you formed your opinions in this case, had you taken the time to try and determine the total amount of Amiodarone that Mr. Priest was given? A: Um, I doubt it.")

The methodology Dr. Friedlander used to review the available medical records and literature to arrive at his diagnosis opinion has none of the hallmarks of a true medical diagnosis. Where, as here, an expert does not have full awareness of a plaintiff's past medical history, this dooms the reliability of their causation opinions, because they cannot have reliably ruled out other potential causes without taking a their full medical history into account. *See, e.g., McNabney v. Lab. Corp. of America*, 153 Fed. Appx. 293, 295 (5th Cir. 2005) (*citing Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 423 (5th Cir. 1987) (medical expert lacked reliability where he was not fully aware of plaintiff's relevant medical history.) As a result, Dr. Friedlander's opinions are not based upon a reliable methodology and should be excluded.

Dr. Friedlander's diagnosis opinion is also unreliable because he admits he cannot rule out other possible causes of Decedent's lung disease other than amiodarone, which is required for medical causation. Courts consistently exclude expert testimony under *Daubert* where an expert did not conduct a proper differential diagnosis. For example, in *Copley v. Smith & Nephew*, the district court excluded testimony of a medical causation expert who "failed to perform a differential diagnosis to exclude other potential causes of Plaintiff's pain." 2000 WL 223404 at *4. The court explained that by failing to exclude other possible causes, the opinion was "not supported by proper scientific methodology." *Id.* Similarly, Magistrate Judge Austin in *Newton v. Roche Labs., Inc.* excluded an expert's specific causation opinions in a pharmaceutical case because he failed to rule out other potential causes, as Dr. Friedlander admits he could not do here. *Newton v. Roche Labs., Inc.*, 243 F. Supp. 2d 672 (W.D. Tex. 2002); *see also McNabney*, 153 Fed. Appx. at 295 ("medical causation experts must have considered and excluded other possible causes of injury" for their opinions to be admissible).

A reliability problem occurs when an expert fails to verify independently data and information used to support an opinion. Dr. Friedlander admits he did not independently review

the radiology studies, he just accepted what physicians and others stated in the medical records rather than conducting his own investigation and analysis of the available tests from the medical records. He looked only at the reports, and not the films themselves, when forming his opinions in this case, because he does not interpret CT scans in his practice. Friedlander Dep. at 163:16-24. Notably, the CT report (attached as **Exhibit D**) lists the radiologist's differential diagnoses and Dr. Friedlander admits he was unable to rule out all of these possibilities, including, for example, the first one the radiologist listed: interstitial pneumonitis. Friedlander Dep. p. 230:15-123 ("I just didn't see anything. I can't say that it's complete[ly] ruled out.... Q: So you didn't rule that out and it's part of your differential? A: Right, right, right.").

Dr. Friedlander also testified that he did not, and could not, interpret the pulmonary function study, which is a key clinical factor in diagnosing AIPT. *Id.* at 206:20-23 (Q: "[W]e talked about the pulmonary function study and you're not able to, sitting here as a physician, interpret that? A: No, but the pulmonologist did.") Because Dr. Friedlander failed to independently review the very studies he relies upon and instead simply takes the report at face value to support his medical diagnosis opinion, it is not reliable and there is rational, scientific basis for his opinions regarding the Decedent's diagnosis and his opinion should be excluded.

As in *King*, Dr. Friedlander did not conduct his own complete factual investigation before forming his opinions, and as in *McNabney*, *Copley* and the other cases cited herein, he did not and could not exclude other possible causes of Plaintiffs' alleged injuries. As a result, his causation and diagnosis opinions are not based upon a reliable methodology and should be excluded. Dr. Friedlander bases these opinions on nothing more than a temporal connection between the aspiration that led to Mr. Priest's death and his purported AIPT months earlier:

Q: And the information that you were going off of in performing your differential were the patient's self-reported symptoms of increased dyspnea?

A: Correct.

Q: And the radiology studies?

A: Correct.

Q: And his temporal history of low amount of Amiodarone?

A: Correct, and weight loss and the absence of other things that would acutely cause him to deteriorate over this period of time.

Friedlander Dep. p. 217:21 – 218:8. A mere temporal connection of use of a particular drug to the alleged injury is not a reliable basis for an expert opinion. *See Wooley v. Smith & Nephew Richards*, 67 F. Supp. 2d 703, 708 (S.D. Tex. 1999) (striking medical expert who asserted a “generic conclusion by making a temporal connection between [plaintiff’s] alleged injuries and the surgical implants.”) In *Wooley*, the court also criticized an expert who “allowed individuals other than himself to select particular records belonging to the plaintiff before he reviewed them. This is not a proper methodology for justifying how [he] reached his conclusions.” *Id.* at 709. Dr. Friedlander did the same here, by his own admission, in not reviewing the full records.

Based on the above deficiencies in Dr. Friedlander’s qualifications and incomplete differential diagnosis, the Court should exclude Dr. Friedlander’s medical diagnosis opinion regarding alleged AIPT. Dr. Friedlander does not have the education, training or experience to offer opinions as to whether Mr. Priest likely had amiodarone induced pulmonary toxicity, and even if he were his opinion would be both unreliable and unsupported by the evidence.

C. Dr. Friedlander’s Opinion that AIPT Caused Mr. Priest’s Death Should Be Excluded Because It Is Speculation Unsupported by the Medical Records or Literature.

It is axiomatic that Plaintiff must establish through competent and reliable expert testimony that Defendant’s amiodarone was the proximate cause of the Decedent’s injuries and death. The nature and function of prescription drugs and the causes of interstitial lung disease clearly fall outside the common understanding of a layperson, and, as such, expert testimony is required to establish medical causation in this case. *Samuel v. Johnson & Johnson*, 2015 WL 10793724, at *4 (E.D. Tex. Aug 14, 2015). It is Plaintiff’s burden to

establish a causal connection between Mr. Priest's ingestion of the amiodarone and Decedent's lung disease and death. *See, e.g., Spears v. United States*, No. 5:13-CV-47-DAE, 2014 WL 258766, at *10 (W.D. Tex. Jan. 23, 2014) (to show causation, a plaintiff must "adduce evidence of a 'reasonable medical probability' or 'reasonable probability' that [the] injuries were caused by the negligence" of the defendant, meaning that it is "'more likely than not' that the ultimate harm or condition resulted from such negligence." (citing *Jelinek v. Casas*, 328 S.W.3d 526, 532–33 (Tex.2010))).

As with Dr. Friedlander's attempt to diagnose Mr. Priest with AIPT, his opinion that amiodarone toxicity caused the events leading to his death is speculative and unreliable. Fed. R. Evid. Rule 702 requires that expert testimony be "the product of reliable principles and methods that are reliably applied to the facts of the case." That is not the case here.

1. Dr. Friedlander's Opinion that Amiodarone Pulmonary Toxicity Was the Cause of Mr. Priest's Dysphagia and Aspiration Is Specious and Unreliable.

The undisputed medical facts in this case, as Dr. Friedlander readily agrees, are that Mr. Priest's death was caused by his aspiration of gastric contents in February 2014 due to his dysphagia (difficulty swallowing), which caused a serious and ultimately fatal infection and septic shock. This is contrary to Dr. Friedlander's report, which states the cause of Mr. Priest's death was the "natural and expected sequelae resulting from pulmonary fibrosis secondary to amiodarone." Friedlander Report, p. 2, ¶ 5. In his deposition, he recanted this opinion from his report, and instead agreed with the consulting pulmonologist's report that diagnosed Mr. Priest with septic shock from aspiration pneumonitis. Friedlander Dep. at. 242:13-24 (Q: And that's what killed him? A: Absolutely.); *Id.* at 268:24-269:2 ("Q: And we know he died because he aspirated gastric contents into his lung? A: Absolutely.") When asked what, then, is his basis for saying in his report that Mr. Priest's death was caused by the natural sequelae to pulmonary

fibrosis, he backed away from that opinion, claiming it was “worded unartfully” by Plaintiff’s counsel, who authored his report. *Id.* at 271:2-7. Dr. Friedlander then clarifies just what his specific causation opinion is as to Mr. Priest’s cause of death:

What I meant to say was that as a result of his respiratory insufficiency, he developed weight loss, difficulty swallowing, that may have been partly due to the steroids which was a treatment for it. So ultimately that’s part of it. And as a result of that he aspirated. And as a result of the aspiration, he developed multiorgan failure as a result of the infection. So it wasn’t that Amiodarone toxicity caused kidney failure, liver failure, and so on. But it was a cascading effect. Does that answer it?

Id. at 271:7-18. Dr. Friedlander admits Mr. Priest’s death was **not** caused by the natural sequelae of AIPT, which “is usually respiratory failure if you die and you get intubated and you can’t be supported even with intubation and artificial respiration.” *Id.* at 272:8-23 (Q: And that was not the path of Mr. Priest’s demise, was it? A: No, because he had an acute insult before that could happen.”)

Dr. Friedlander’s re-worked specific causation opinion first expressed in his deposition attributing Mr. Priest’s dysphagia, aspiration, resulting septic shock and death to AIPT is not only outside his medical expertise as a cardiologist, but his opinion lacks any proper medical basis and should be excluded for this reason as well.

2. *Dr. Friedlander’s Opinion that AIPT Caused the Events Leading to Priest’s Death Is Speculation Not Corroborated by Any Medical Record or Literature.*

Dr. Friedlander’s opinion that Mr. Priest’s swallowing difficulty, a.k.a. dysphagia, was caused by AIPT and not some other unrelated etiology such as medullary failure, is utter speculation not supported by any medical record in this case or a single article that Dr. Friedlander could identify. If permitted, Dr. Friedlander would testify that AIPT caused Mr. Priest’s dysphagia, which caused the aspiration of gastric contents, which led to septic shock, which led to multi-organ failure and his eventual death. This opinion is nothing more than a

theory or hypothesis, and his testimony fails to rise to the level of reasonable scientific certainty. Dr. Friedlander was unable to identify anything in the medical records or medical literature that even suggests a connection between Mr. Priest's purported diagnosis of AIPT to his later developed dysphagia or aspiration. Without any foundation in the medical records or literature, Dr. Friedlander's opinion is speculation and should be excluded. *See Black*, 171 F.3d at 310; *see also Guidroz-Brault v. Missouri Pacific R. Co.*, 254 F.3d 825, 829 (9th Cir. 2001) ("Rule 702 requires that expert testimony relate to scientific, technical, or other specialized knowledge, which does not include unsupported speculation and subjective beliefs.")

As with his other opinions in this case, when the conclusory statements are peeled away and the underlying basis for his opinion is questioned, Dr. Friedlander has nothing to offer and the "medical certainty" is reduced to mere possibilities.

Q: ... And nowhere in the literature does it say that steroids cause dysphagia, does it?

A: I don't know but what I'm saying is...**I'm raising that as a possibility because one of the doctors raised it as a possibility. So I'm parroting what they said.** *Id.* at 284:7-15.

Q: You are not going to say that you hold the opinion that steroids cause dysphagia?

A: I'm saying that it was stated and that's not unreasonable because we know steroids can cause muscle weakness. So I'm saying that's certainly a possibility.

Id. p. 285:11-17. Testifying to mere possibilities and parroting what others may have said is not what Rule 702 requires for the admission of expert opinion testimony.

In addition, because of its speculative nature this testimony would not be helpful to a jury. Dr. Friedlander acknowledges his entire opinion hangs by the thread of a connection between Amiodarone lunch toxicity and dysphagia:

Q: You would agree that the aspiration pneumonitis is related to the dysphagia, correct?

A: Yes, it was documented that he aspirated.

Q: And if there is not a connection between the dysphagia and Amiodarone then the entire sequelae that you are opining about goes away?

A: It makes it much more likely, but then I have to ask the question and it's somewhat rhetorical. Why did he have dysphagia? *Id.* at 207:17 – 208:5.

Q: What is the differential diagnosis of dysphagia, doctor?

A: Oh, goodness, it would be many things, stroke, which he didn't have. He was on steroids. Steroids can cause muscle weakness and may, I'm not a gastroenterologist. It may be a potential etiology for that... Did he have trouble swallowing because he was trying to breath at the same time, possibilities. **I'm not there, I'm not taking the history, so it's hard for me to understand precisely what the symptoms were and how they relate.** *Id.* at 190:12-25.

Q: Are you an expert in dysphagia?

A: No, but I stayed at a Holiday Inn last night."

Id. at 191:2-5.

How can Dr. Friedlander be put before the jury as an expert to opine on the cause of death, which he agrees is due to the dysphagia and the resulting aspiration, when he himself cavalierly dismisses having any expertise in the subject matter and admits he cannot state "what the symptoms were and how they relate." *Id.* at 190:12-25. Dr. Friedlander should not be allowed to cloak a clearly speculative specific causation opinion under the auspices of "medical certainty." Dr. Friedlander offers nothing other than his *ipse dixit* opinion that this unfortunate series of events was caused by AIPT and his specific causation opinions warrant exclusion.

Additionally, Dr. Friedlander's opinion that Mr. Priest's purported AIPT was irreversible is purely speculative and unreliable. When asked what is the basis for this opinion, he merely responds, "He died." *Id.* at 237: 6-15. Dr. Friedlander does not point to any evidence in the medical record or any scientific literature to support his contention that Mr. Priest's was irreversible. When asked if amiodarone pulmonary toxicity is a reversible condition, Dr. Friedlander stated "of course, it's reversible...it can be reversible." *Id.* at 246:6-8. His opinion

that Mr. Priest's alleged AIPT was irreversible is as baseless and conclusory as his opinion that Mr. Priest had AIPT to begin with. In giving this opinion, Dr. Friedlander also ignores the testimony of Dr. Batrice, Mr. Priest's internist and treating physician at his final two admissions, that he did not have pulmonary toxicity at all. *Id.* at 240.

D. Dr. Friedlander's Life Expectancy Opinion Is Speculative and Unreliable.

Dr. Friedlander's opinions on Mr. Priest's life expectancy are not "based upon appropriate methodology as *Daubert* commands." *King*, at 836. Dr. Friedlander testified "[a] normal 70-year old probably has a life expectancy into his late 80's. I would have to look that up, don't hold me to a specific number, but I'm guessing that's what the tables would show." Friedlander Dep., at 297:12-16. Dr. Friedlander bases his life expectancy opinions on a vague reference to Social Security tables, which he admits not having looked at. *Id.* Without any reasoning, analysis, or data for a 79-year old like Mr. Priest who smoked for 40 years and had long-standing Chronic Obstructive Pulmonary Disease and underlying heart disease, Dr. Friedlander states "I'm not saying he would have had an entirely normal life expectancy, but it would have been substantial. If normal takes him to the late 80's, then I give him to the mid 80's." *Id.* at 297: 19-23. Bare reliance on social security tables applicable to all 79 year olds fails to consider Mr. Priest's complex medical history and comorbidities, which apparently Dr. Friedlander did not. His opinion that Mr. Priest's life expectancy would have been normal but for his purported AIPT lacks any of the hallmarks of a valid medical opinion and would not help the jury because he used absolutely no methodology specific to Mr. Priest, and it appears he was simply guessing off the cuff. Thus, this opinion should be excluded.

E. Dr. Friedlander's Opinions Would Not Be Helpful to the Jury.

Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Daubert*, 509 U.S. at 591-92, (internal citations and

quotation marks omitted). Dr. Friedlander's diagnosis opinion that Mr. Priest had AIPT is based purely on the temporal proximity of the amiodarone prescriptions and the alleged symptoms that developed later. Dr. Friedlander points to no tests or evidence that he independently investigated or verified to support his diagnosis opinion. And when this specious diagnosis is combined with an unfounded opinion that the purported AIPT led to Mr. Priest's series of medical events, i.e. AIPT-induced dysphagia that caused Mr. Priest to aspirate and become septic, the jury is left to speculate right along with Dr. Friedlander because there is absolutely no evidence, and certainly no proof to a reasonable degree of medical certainty, to help them reach a decision in this case.

IV. CONCLUSION

For the foregoing reasons, Dr. Friedlander's opinion about Mr. Priest's diagnosis and death being caused by amiodarone pulmonary toxicity is unreliable, speculative, and far from reasonable medical probability. Sandoz therefore respectfully requests that expert opinions of Richard Friedlander, M.D. related to whether Mr. Priest can be diagnosed with amiodarone induced pulmonary toxicity and whether amiodarone induced pulmonary toxicity proximately caused his aspiration and death should be excluded or limited, because: (1) Dr. Friedlander is not qualified to offer opinions as to pulmonary toxicity; (2) his opinion purporting to diagnose Mr. Priest with AIPT is unreliable; (3) his opinion that the aspiration and resulting sepsis which led to Mr. Priest's death, was caused by AIPT is speculative and unreliable and is outside his area of expertise; (4) his life expectancy opinion is likewise speculative and unreliable, and thus inadmissible under Rule 702 and *Daubert*. Sandoz submits herewith its Proposed Order outlining the specific opinions to be excluded.

Because the factual, legal and medical issues presented by this Motion are complex, Sandoz respectfully requests a hearing on this Motion pursuant to L.R. 7(h).

Respectfully submitted this 22nd day of September, 2017.

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CERTIFICATE OF CONFERENCE

I hereby certify that counsel for Plaintiff Margaret Halton Priest and Defendant Sandoz Inc. have conferred on the above Motion to Exclude Testimony of Richard Friedlander, M.D., and counsel for Plaintiff opposes the motion.

/s/ Sara K. Thompson

CERTIFICATE OF SERVICE

I hereby certify that this document was served via mail and email on this 22nd day of September, 2017:

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